Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in

the application:

Listing of Claims:

1. (Currently Amended) An assay for determining the concentration of rapamycin or

a rapamycin analog concentrations in a sample, the rapamycin or rapamycin

analog being capable of binding to FKBP12 protein or a binding domain thereof, the

assay comprising:

(i) contacting the sample with PKBP12 FKBP12 protein, or with a

rapamycin binding fragment of said PKBP12 the FKBP12 protein that

maintains the rapamycin binding properties, for a time period and

under conditions allowing formation of rapamycin/FKBP12 complex;

(ii) contacting the rapamycin/FKBP12 complex with a complex-

binding domain of mTOR for a time period and under conditions

enabling binding of the complex to the said complex-binding domain;

(iii) detecting the amounts of said complex-binding domain that is

bound to the rapamycin/FKBP12 complex;

(iv) comparing the amounts detected in (iii) to a calibration curve,

thereby determining the rapamycin concentration[[s]] of the

rampamycin in the sample.

SAGI-EISENBERG Serial No. 10/584,770 Page 5 of 33

2. (Currently Amended) The assay [[of]] according to claim 1, wherein the said

rapamycin being native rapamycin or synthetically produced rapamycin, or any

analog of the two.

3. (Currently Amended) The assay [[of]] according to claim 1, wherein the said

sample is a liquid, a solid or a semi solid sample.

4. (Currently Amended) The assay [[of]] according to claim 3, wherein the said

liquid sample is a body fluid selected from the group consisting of plasma, blood,

serum, urine, sperm[[, or]] cerebral spinal fluid.

5. (Currently Amended) The Assay of claim 3, wherein the said solid sample is a

tissue.

6. (Currently Amended) The assay of claim 3, wherein the said sample is semi-solid

sample selected from the group consisting of tissues or feces.

7. (Currently Amended) The assay according to claim 4, wherein the said liquid

sample is mammalian blood.

8. (Currently Amended) The assay according to claim 1, wherein the said FKBP12

protein is a full FKBP12 protein being a 12kDa protein or a fragment of FKBP12

protein that maintains the rapamycin binding properties of the full protein.

SAGI-EISENBERG Serial No. 10/584,770 Page 6 of 33

- 9. (Original) The assay according to claim 1, wherein the FKBP12 protein or the fragment thereof is immobilized on a solid substrate.
- 10. (Currently Amended) The assay according to claim 9, wherein the said solid support is a 96-well microtiter plate.
- 11. (Currently Amended) The assay according to claim 10, wherein the said microtiter plate is blocked by non specific protein.
- 12. (Currently Amended) The assay according to claim 1, wherein the said detection is achieved by an ELISA reader.
- 13. (Currently Amended) The assay [[of]] <u>according to claim 1</u>, wherein <u>the said</u> complex binding domain of mTOR is a FRB fragment.
- 14. (Currently Amended) The assay according to claim 13, wherein the said FRB fragment is directly bound to a detectable label.
- 15. (Withdrawn) The assay according to claim 13, wherein said FRB fragment is indirectly bound to a detectable label.

SAGI-EISENBERG Serial No. 10/584,770

Page 7 of 33

16. (Currently Amended) The assay according to claim 14, wherein the said label is

capable of generating a signal detectable by a technique selected from the group

consisting of coloremtry, spectrophotometry, fluorospectrophotometry, gaseometry

[[or]] and radiospectrometry.

17. (Currently Amended) The assay according to claim 16, wherein the said

detectable label is an enzyme capable of producing, in the presence of a suitable

substrate, a color reaction.

18. (Currently Amended) The assay according to claim 17, wherein the said

enzyme is alkaline phosphatase or HRP enzyme.

19. (Currently Amended) The assay according to claim 18, wherein the said

enzyme is used with a color-forming reagent or reagents selected from the group

consisting of p-nitrophenyl phosphate, hydrogen peroxide, o-phenylenediamine and

3,3',5,5'-Tetramethylbenzidine.

SAGI-EISENBERG Serial No. 10/584,770 Page 8 of 33

- 20. (Currently Amended) A kit for determining rapamycin concentrations, or rapamycin analog concentrations in a sample, the kit comprising:
 - [[(i)]] <u>a FKBP12</u> PKBP12 protein or a rapamycin binding portion thereof immobilized on a solid substrate; and
 - [[(ii)]] a complex-binding domain of mTOR linked to a label that may be detected or that may generate a signal.
- 21. (Currently Amended) The kit [[of]] <u>according to claim 20</u>, wherein <u>the said</u> complex binding domain of mTOR is provided in separate vessel.
- 22. (Currently Amended) The kit according to claim 20, wherein the said complex binding domain of mTOR is the 93-amino acids FRB domain, linked to a label that can be detected or that can generate a signal.
- 23. (Currently Amended) The kit according to claim 22, wherein the said label is capable of generating a signal detectable by a technique selected from the group consisting of coloremtry, spectrophotometry, fluorospectrophotometry, gaseometry [[or]] and radiospectrometry.
- 24. (Currently Amended) The kit according to claim 22, wherein the said label is capable of producing a colorimetric reaction.

25. (Currently Amended) The kit according to claim 22, wherein the said label is an enzyme capable of producing, in the presence of a suitable substrate, a colorimetric

reaction.

- 26. (Currently Amended) The kit according to claim 25, wherein the said enzyme is alkaline phosphatase enzyme or HRP enzyme.
- 27. (Withdrawn) The kit according to claim 22 further comprising antibodies which are conjugated to an enzyme capable of producing a colorimetric reaction.
- 28. (Withdrawn) The kit according to claim 27, wherein said antibodies are directed against the FRB fragment.
- 29. (Withdrawn) The kit according to claim 24, wherein said antibodies are directed against a tag to which FRB or FRB fragment are being conjugated.
- 30. (Withdrawn) The kit according to claim 22 further comprises the label required to generate a signal detectable by a technique selected from coloremtry, spectrophotometry, fluorospectrophotometry, gaseometry or radiospectrometry.
- 31. (Currently Amended) The kit according to claim 22, further comprising preweighed samples of rapamycin and rapamycin analogs for producing calibration curves.

SAGI-EISENBERG Serial No. 10/584,770 Page 10 of 33

32. (Withdrawn) The assay according to claim 15, wherein said label is capable of generating a signal detectable by a technique selected from coloremtry, spectrophotometry, fluorospectrophotometry, gaseometry or radiospectrometry.